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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/516,500
Filing Date: December 02, 2004
Appellant(s): HANCKE OROZCO ET AL.

Mark Pohl
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/13/2007 and reply brief filed on 09/04/2007, 11/08/2007, appealing from the final office action mailed 01/19/2007.

(1) Real Party in Interest

The real party in interest is HP ingredients, Inc., a Florida corporation.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of invention is correct with exception of:

(1) The structure shown on page 2, line 15 for the compound is unclear as the substituents carbon #3 and carbon #4, carbon #3 should be CH_2OH and carbon #4 should be H.

(6) Grounds of Rejection to be Reviewed on Appeal

(1) the rejection of claims 53-54, 63, and 66-72 under 35 U.S.C. 102(b) over Wheelock et al., US 5,833,994.

(2) the rejection of claims 53-54, 65-72 under 35 U.S.C. 102(b) over Wheelock et al., US 6,140,063.

(3) the rejection of claims 53-54, 64-72 under 35 U.S.C. 102(b) over Babish et al., WO 96/17605.

(4) the rejection of claims 53-54 and 65-72 under 35 U.S.C. 102(b) over Wheelock et al., WO 98/30213.

(5) the rejection of claims 53-54 and 66 under 35 U.S.C. 102(b) over Nanduri et al., US 6,410,590.

(6) the rejection of claims 53-54, 64-72 under 35 U.S.C. 102(b) over Nanduri et al., US 6,486,196.

(8) the rejection of claims 53-54 and 65-72 under 35 U.S.C. 102(b) over Nanduri et al., US 2002/0016324.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(**8) Evidence Relied Upon**

Wheelock et al., US 5,833,994.

Wheelock et al., US 6,140,063.

Babish et al., WO 96/17605.

Wheelock et al., WO 98/30213.

Nanduri et al., US 6,410,590.

Nanduri et al., US 6,486,196.

Nanduri et al., US 2002/0016324.

Babish et al., US 2002/0077350.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 53-73 are rejected under 102(b). This rejection is set forth in a prior Office Action, mailed on 01/19/2007 and 03/16/2006.

(a) Claims 53, 54, 63, 65-66 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Wheelock et al., US 5,833,994. On column 21, lines 49-52, Wheelock teaches the compound “Andrographolide” which is extracted from the Andrographis Paniculata plant which has activity as treating AIDS, cancer, viral infection.

(b) Claims 53-54, 65-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Wheelock et al., US 6,140,063. On column 22, lines 35-38, the compound “Andrographolide” which is extracted from the Andrographis Paniculata Plant which has activity as treating AIDS, cancer, viral infection.

(c) Claims 53, 54, 64-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Babish et al., WO 96/17605. On page 16, lines 15-16, the compound "Andrographolide" is encompassed by the instant compound claimed with the same activity i.e. Alzheimer, AIDS, see page 9,”lines 12-24. Therefore, the instant claims are anticipated with the same utility by Babish et al.

(d) Claims 53-54 and 65-72 are rejected under U.S.C. 102(b) as being anticipated by Wheelock et al., WO 98/30213. Wheelock has shown on page 32 that "Andrographolide" is obtained from the same family of plant Andrographis Paniculata having the activity such as AID”, and cancer. Therefore, since this

reference repeats the name “Andrographolide” over and over, then the structure of “Andrographolide” should be the same as the structure from the

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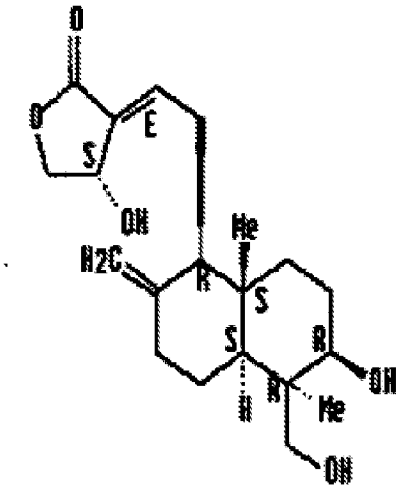
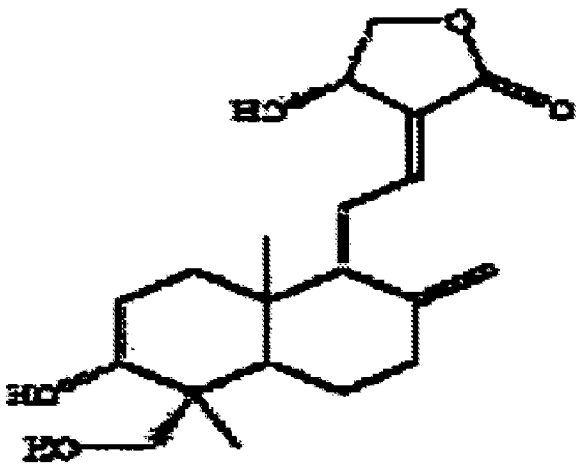
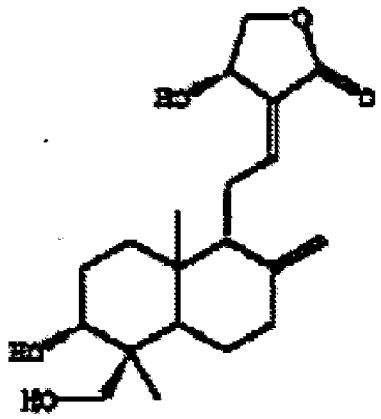


(e) Claims 53-54 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Nanduri et al., US 6,410,590. On column 8, lines 10-25, the compound of formula (II)



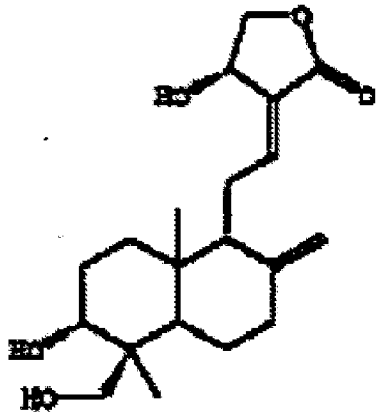
anticipated the instant compound claimed which is obtained from the same family of plant Andrographis Paniculata (column 2) having the activity such as autoimmune diseases, AIDS, and cancer. Therefore, since the structure and the name is the same as the instant claims, there is no difference.

(f) Claims 53-54, 64-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Nanduri et al., US 6,486,196. On column 2, the compound "Andrographolide"



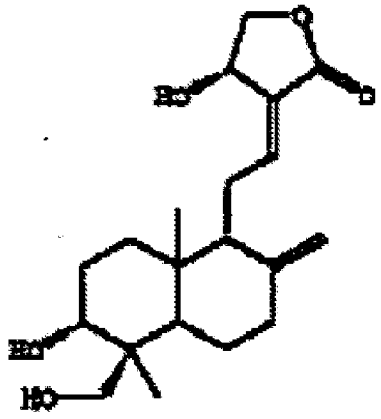
disclosed, which is extracted from the same family of plant Andrographis Paniculata having activity against Alzheimer's, AIDS, and cancer. Therefore, since the structure and the name are the same as the instant claims, there is no difference.

(g) Claims 53-54, 65-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Nanduri et al., US 2002/0016324. On column 1, the compound "Andrographolide"



disclosed, which is extracted from the same family of plant Andrographis Paniculata having activity against Alzheimer's, AIDS, psoriasis, cardiovascular disorders and cancer. Therefore, since the structure and the name is the same as the instant claims, there is no difference.

(f) Claims 53-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Babish et al., US 2002/0077350. On sheet 2, the compound [C3], "Andrographolide"



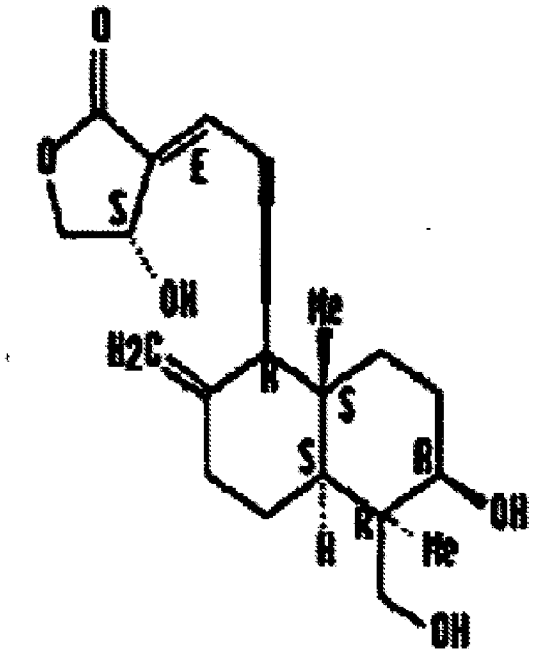
is encompassed by the instant compound claimed, which is extracted from the same family of plant Andrographis Paniculata having activity against antihyperlipidemia (one factor of syndrome X), see page 6, paragraph 49, inflammatory disease, Alzheimer's, AIDS, see page 1, paragraph 1-5. Therefore, the instant claims are anticipated with the same utility by Babish et al.

(10) Response to Argument

1) **The summary of appellants' arguments is that** the art cited does not teach the instantly claimed compound, which is **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone**

It is examiner's position that the prior art of record does teach the claimed compound, Andrographolide, which IUPAC name is **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone**

The structure of compound is shown to be



, as registry (RN) No. **5508-58-7**. Thus, the compound of the reference is the same as the claimed compound, “Andrographolide”, even though different structures are disclosed.

2) Appellants argue that Babish fails to teach every element of claim 53

Claim 53. A method comprising:

i) diagnosing in a patient a disease selected from the group consisting of : Alzheimer’s disease; Acquired Immune Deficiency syndrome; and autoimmune disease, and ii) administering to said patent 3-[2-[decahydro-6-hydroxy-5-

(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone in an amount effective to combat said disease. Further, Appellants argue that the examiner alleges that Babish (1996) teaches a compound "having activity as Alzheimer's, AIDS" the examiner is incorrect because Babish (1996) fails to mention Alzheimer's, nor AIDS, nor indeed any therapeutic action at all.

It is Examiner's position that Babish (1996) states on page 7, lines 6-12 that lowering kinase expression can inhibit HIV-1 mediated cell death for patients with AIDS, that it can inhibit phosphorylation of amyloid precursor protein which can delay the onset of Alzheimer's, and that other diseases can be treated using the present invention. See also page 34, lines 12-15 and 20-26. Thus Babish (1996) clearly does teach therapeutic action.

Appellants argue that the examiner alleges that Babish (2002) at 5 fails to mention clinical use as an anti inflammatory, or to treat Alzheimer's disease, or for anti-hyperlipidemia, or as an anti tumor agent, or to treat colon cancer.

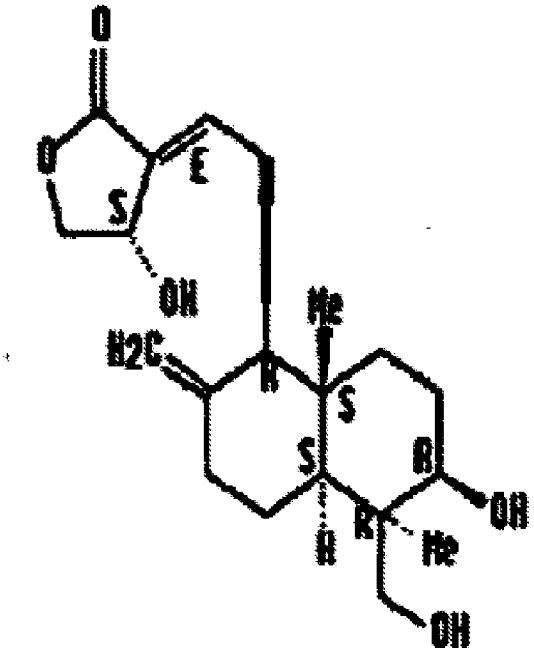
It is examiner's position that Babish 2002/068098 (now U.S. patent 6629835) teaches that the disclosed agents are useful for promoting anti inflammatory effects in response to physical or chemical injury (see abstract). Babish 2002/0068098 further provides a list of diseases that are appropriate targets for these agents in table 2, page 5, paragraph 42. Further guidance as to these agents' use in treatment of Alzheimer's disease is found in page 8, paragraphs 74-75 (example 7); treatment of colon cancer is taught on page 8,

paragraphs 76-77 (example 8). Babish 2002/0077350 teaches that the disclosed agents are useful for promoting anti inflammatory effects in response to physical or chemical injury (see abstract). Babish 2002/0068098 further provides a list of disease that are appropriate targets for these agents in table 2, page 7, paragraph 57. Further guidance as to these agents' use in treatment of Alzheimer's disease is found in page 10, paragraphs 92-93 (example 11); treatment of colon cancer is taught on page 10, paragraphs 94-95 (example 12).

3) **Appellants argue that** Babish teaches a broad variety of chemical compounds. These compounds, however, are different from the claimed compound.

It is examiner's position that Babish teaches a broad variety of chemical compounds including "Andrographolide", the IUPAC name for which is **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone**

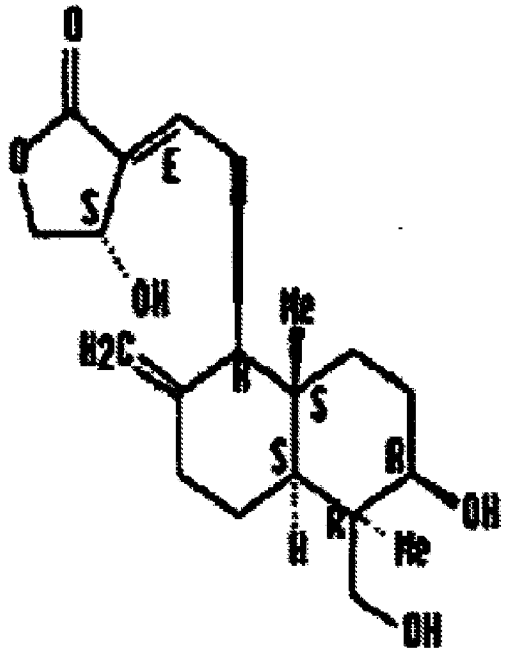
The structure of compound is shown to be



, as registry (RN) No. **5508-58-7**. Thus, the compound of the references is the same as the claimed compound, “Andrographolide”, even though different structures are disclosed. The structure shown in Babish et al., US 2002/0077350 is a typographical error due to a further reading within the US 2002/0077350 disclosing how the compound was made leads the ordinary skill artisan to the conclusion that the disclosed structure is a typographical error and was meant to be “Andrographolide” with the registry No. 55-0-58-7 and the chemical name **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone.**

4) Appellants argue that the claimed compound is **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone.** In contrast, Babish (1996) teaches compounds which differ in a number of aspects. See e.g., Babish (1996) at fig. 6 (reproduced below).

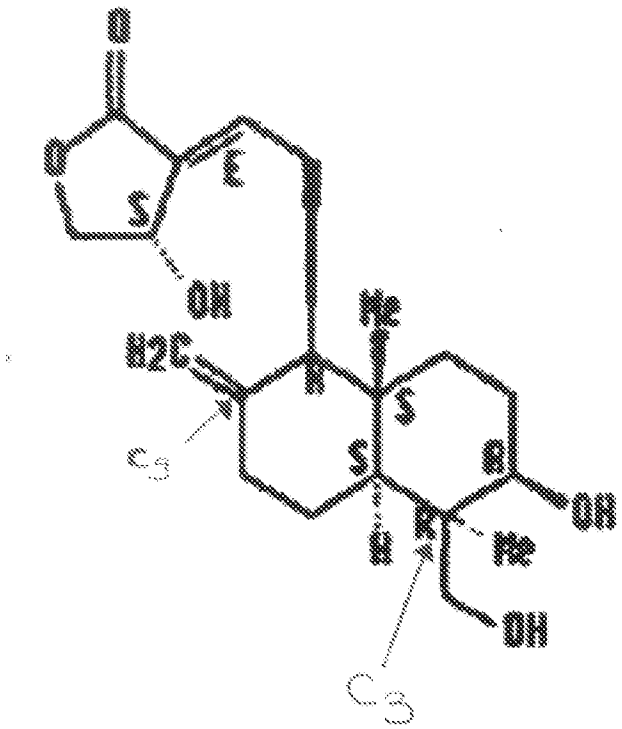
It is examiner's position that the examiner agrees that this compound **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone** has structure



, which is also known as "Andrographolide".

5) Appellants argue that for example, the prior art compounds have an R group at C1, the prior art compounds lack the CH3 and CH2OH groups at C3, and the prior art compounds lack the double bond at C9.

It is examiner's position that the prior art compound has the structure below



, which has CH3 and CH2OH groups at C3 and double bond at C9.

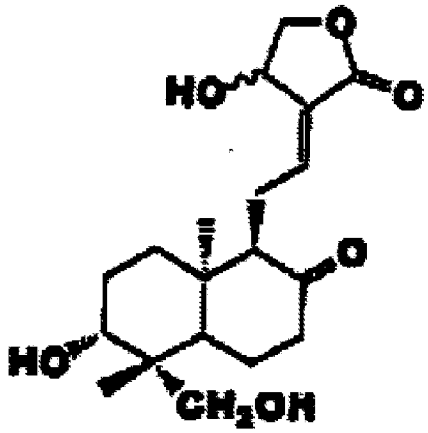
6) Appellants argue that Babish et al., US 2002/0068098 (2002) and Babish et al., US 2002/077350 (2002) each teach a compound which is different from the claimed compound.

It is examiner's position that Babish et al., US 2002/0068098 (2002) teaches "Andrographolide" on page 4, which has shown that Androgprapholide is obtained from the same family of plant Andrographis Paniculata.

Babish et al., US 2007/077350 (2002) teaches "Andrographolide" on page 5, which has shown that andrographolie is obtained from the same family of plant andrographis paniculata.

7) Appellants argue that the examiner concedes that Babish (2002) teaches a different structure.

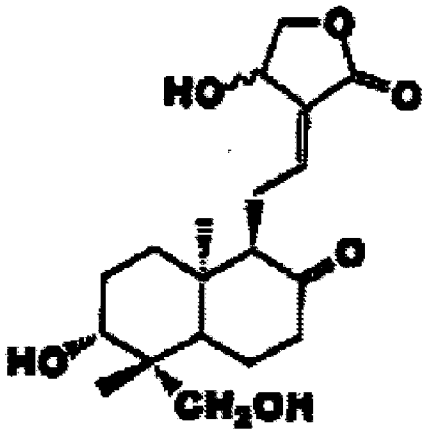
It is examiner's position that Babish US 2002/068098 disclosed



on sheet 2, Fig. [B3], which has the (=O) and is a typographical error. Babish on page 4 has shown that andrographolide is obtained from the same family of plant Andrographis Paniculata having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia. Since the compound comes from the same source and has

same properties, the compound shown in the reference must be a typographical error.

Babish US 2007/077350 disclosed



on sheet 2, the compound [C3], which has the (=O) and is typo. Babish on page 5 has shown that andrographolide is obtained from the same family of plant Andrographis Paniculata having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia, antitumor, colon cancer.

8) Appellants argue that Babish fails to teach every element of claim 66. independent claim 66 is an treatment requiring "an amount effective to affect said patient's immune system function." The examiner fails to allege where Babish enables or even mentions-the claimed amount.

It is examiner's position that Babish US 2002/068098 disclosed on page 4 "Andrographolide", which is obtained from the same family of plant

Andrographis Paniculata having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia. Therefore, the amount to be effective to affect the patient's immune system is inherently there.

Babish US 2007/077350 disclosed on page 5 has shown that "Andrographolide", which is obtained from the same family of plant Andrographis Paniculata having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia, antitumor, colon cancer. Therefore, the amount effective to affect the patient's immune system is inherently there.

9) Appellants argue that Babish fails to teach every element of claim 73. Independent claim 73 is a treatment for Syndrome X. The examiner fails to allege where Babish teaches or even mentions-Syndrome X.

It is examiner's position that Babish US 2002/068098 disclosed on page 4 "Andrographolide", which is obtained from the same family of plant Andrographis Paniculata having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia. Further guidance as to these agents' use in treatment Irritable bowel Syndrome is found on page 8, example 9, paragraph 78. It is well know by the ordinary artisan that one part of syndrome X is irritable Bowel syndrome.

Babish US 2002/068098 disclosed Babish on page 4 "Andrographolide", which is obtained from the same family of plant Andrographis Paniculata having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia.

Further guidance as to these agents' use in treatment of Irritable bowel Syndrome is found on page 11, example13, paragraph 96. It is well know by the ordinary artisan that one part of syndrome X is irritable Bowel syndrome.

10) Applicants argue that Wheelock fails to teach every element of claim 53.

Wheelock fails to anticipate the claim because it fails to teach the claimed compound.

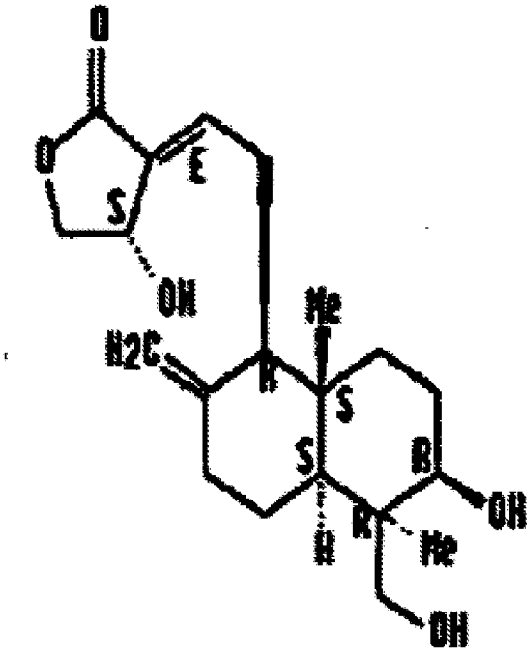
It is examiner's position that Wheelock WO '213 disclosed on page 32 that "Andrographolide" is obtained from the same family of plant Andrographis Paniculata having the activity such against AIDS, and cancer. The structure that Appellant mentioned on page 11 of appeal brief is the first effective compound of claim 15 of WO '213. "Andrographolie" is the second compound of claim 15, further shown in claims 17 and 21.

Wheelock US '994 disclosed on column 21, lines 49-52, the compound "Andrographolide" which is extracted from the Andrographis Paniculata plant which has activity as treating AIDS, cancer, and viral infection. The structure that applicant mentioned above is not considered to be Andrographolide.

11) Appellants argue that the evidence of record teaches that the compound(s) called "Andrographolide" has (have) a chemical structure(s) which is (are) different from the claimed compound. Further, appellants argue that the evidence of record corroborates the inventor's testimony that the term

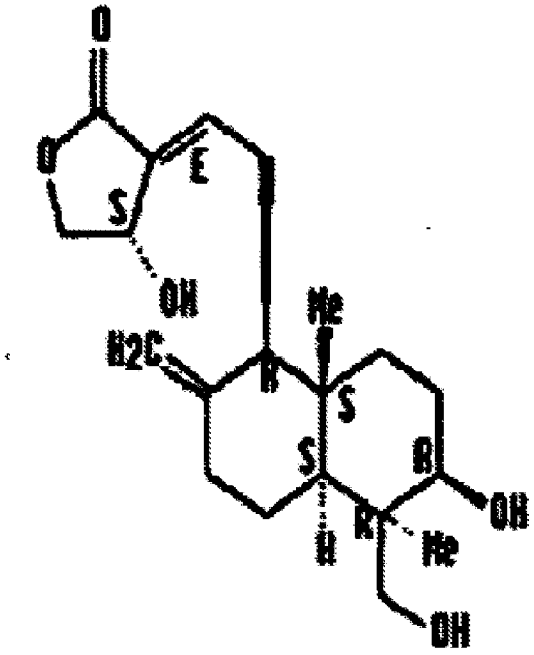
"Andrographolide" is ill-defined and has different meanings in the art see J.L. Hancke, Rule 132 declaration (9 September 2006).

It is examiner's position that it has already been argued that "andrographolide" as shown in Babish 2002/0077350 is a typographical error and this was discussed on page 18 of this examiner's answer. The declaration of (September 2006) by John Hancke has already been reviewed and considered in the previous office action and is not deemed persuasive due to the number of the other references that discuss " andrographolide" as having the same structure as the



12) Appellants argue that first, “the STN REGISTRY” is not of record in this proceeding. Second, no evidence of record indicates that Geoffrey D. Wheelock and his co-inventors in fact intended the term “andrographolide” to mean the “STN REGISTRY” compound, rather than the compound taught by Babish nor the compounds taught by Nanduri.

It is examiner’s position that “ the STN REGISTRY” is an online database that was used in final office action dated on 01/19/2007. it is not itself a reference. It is a chemical compound data base. It is shown that one compound name “Andrographolide” having chemical name: **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone** has structure



, which comes from the plant

"Andrographis Paniculata". Babish 2002/0077350 teaches "Andrographolide" obtained from "Andrographis Paniculata", page 5, column 2, paragraph 45.

13) Appellants argue that Wheelock fails to teach every element of claim 66.

It is examiner's position that as previously stated Wheelock WO '213 teaches use of "Andrographolide" to treat a patient with HIV, which is a deficiency in a patient's immune system on pages 12-18, example 1. Wheelock US '994 teaches use of "Andrographolide" to treat a patient with HIV, which is a deficiency in a patient's immune system on pages 8-13, example 1.

14) Appellants argue that Wheelock fails to teach every element of claim 73.

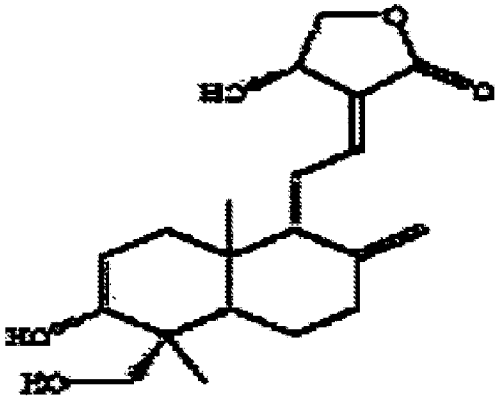
It is examiner's position that Syndrome X is know to ordinary artisan to include disease in conditions such as HIV, viral infection, and cancer, which are taught in Wheelock WO '213 on page32 and Wheelock US '994 on column 21, lines 49-52.

15) Appellants argue that Nanduri fails to teach every element of claim 53.

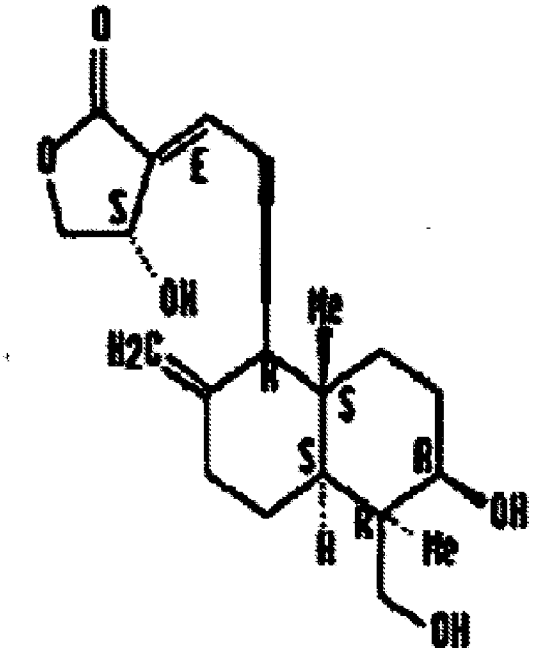
It is examiner's position that Nanduri 6,410,590 teaches "Andrographolide", which is obtained from the same family of plant "Andrographis Paniculata" (column 2) having activity such as treatment of autoimmue disease, HIV and cancer. Nanduri 6,486,196 teaches "Andrographolide", which is obtained from the same family of plant "Andrographis Paniculata" (column 2) having activity against diseases such as Alzheimer's, HIV and cancer.

Nanduri 2002/0016324 teaches “Andrographolide”, which is obtained from the same family of plant “Andrographis Paniculata” (column 1) having activity against diseases such as HIV, psoriasis, cardiovascular disorders and cancer.

16) Appellants argue that Nanduri fails to teach the claimed compound. Nanduri teaches “Andrographolide having the formula (I), see e.g., US ‘590 at 2:26-43, and “Andrographolide having the general formula (I),” see id, at 1:14-30. **It is examiners position that** the “Andrographolide” compound in Nanduri ‘590 has the structure

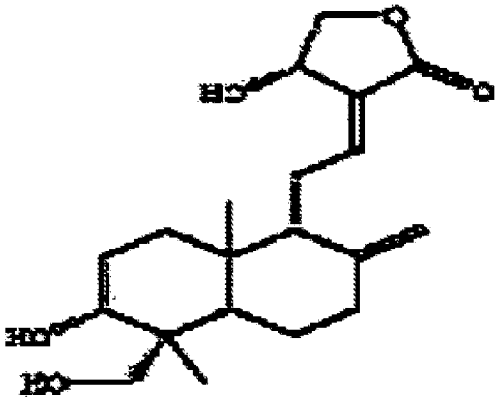


, which is the same as the named compound on claim 53, **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone.** The claimed compound **is 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone,** which has the structure



, which is the same as the

Nanduri structure



17) Appellants argue that Nanduri fails to teach every element if claim 66.

It is examiner's position that as previously stated Nanduri '590 teaches use of "Andrographolide" to treat a patient with HIV, which is a deficiency in a patient's immune system on column 30, lines 37-64. Nanduri '196 teaches use of "Andrographolide" to treat a patient with HIV, which is a deficiency in a patient's immune system on column 43-44. Nanduri '324 teaches use of "Andrographolide" to treat a patient with HIV, which is a deficiency in a patient's immune system on page 43, paragraph 428.

18) Appellants argue that Nanduri fails to teach every element of claim 73.
It is examiner's position that Syndrome X is know to ordinary artisan to include disease in conditions such as syndrome X, Alzheimer's, autoimmune disease, HIV, AIDs, anti cancer, which teach in Nanduri '590 on abstract and Nanduri '196 on columns 1-2, lines 55-67 and 1-10 and Naduri '324 on page 1, paragraphs 3-4.

19) Appellants argue that it would not have been obvious to modify any of the prior art compounds to make the claimed compound, and that it would not have been obvious to use such a modified compound for the claimed uses.
It is examiner's position that the prior art makes the compound. They do not have to modify the compound. The compound is disclosed in, i.e. g., Nanduri '590, column 2, formula (II).

20) Appellants argue that the claims are drawn to methods to treat AIDS, syndrome X, non-autoimmune Alzheimer's disease, and autoimmune disease. In contrast, the art of record fails to teach these therapeutic uses. See J.L. Hancke, Rule 132 declaration (9 September 2006).

It is examiner's position that the claims are drawn to a method of treatment AIDS Alzheimer's disease, autoimmune disease, syndrome X. Nanduri '590 teaches "Andrographolide" having activity against diseases such as autoimmune disease, HIV and cancer. Babish '605 teaches "Andrographolide" having activity against such diseases as Alzheimer's and AIDS.

Thus the references above teach the Andrographolide (i.e. **3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone** compound with all the claimed limitations to treat the same diseases as the instant claims. Therefore, the rejections are proper.

Respectfully submitted,

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06/11/2009
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